

REMARKS

Review and reconsideration of the application in view of Applicants' amendments and remarks are respectfully requested. Applicants herein amend Claims 3, 9, and 17 for clarity. Claim 3 is amended to be singly dependent from claim 1, claim 9 is amended to depend from claim 2 for clarity, and claim 17 is amended as requested by the Examiner to correct an informality. Applicants submit all of claims 1-10 and 12-26 are in condition for allowance for at least the reasons set forth herein.

Consideration of the amendment and remarks after final is proper under 37 C.F.R. §1.116 because 1) the claim amendments clarify the claimed subject matter and do not add new matter or raise new issues; 2) the remarks address a new ground of rejection first raised in the Office Action mailed February 27, 2004; and 3) the amendment and remarks place the application in condition for allowance, or at least in better condition for appeal. Entry and consideration of the remarks are thus respectfully solicited.

Claims 17-26 have been objected due to informalities. Claim 17 is amended as suggested by the Examiner at page 2, paragraph 2, of the Office Action. The remaining claims depend from claim 17. Reconsideration and withdrawal of the rejection are in order, and are respectfully solicited.

Claims 1-10 and 12-26 have been rejected under 35 USC § 103(a) over Kirollos et al. (US 6,284,198) in view of Morita et al. (US 4,668,714). For at least the following reasons, the rejection is traversed.

Kirollos et al. is directed to a warning sign device having a support, and a coating on the support wherein the coating contains a chromographic reagent that changes color in the presence of a polluting gas. *See abstract.* The device functions as a self-appearing warning sign in the presence of toxic gasses, as described in the specification at least at col. 4, lines 12-16. The warning sign is the coating on the support. The chromographic reagent in the coating causes the coating to change color commensurate with exposure level to a gas. The exposure level can be determined over a measurable exposure time by

correlation to a known color chart or by electronic determination of the level of contaminant. *See* col. 4, lines 25-34. As admitted in the Office Action, Kirollos et al. does not disclose or suggest use of the warning device for the detection of radiation, and does not disclose or suggest the use of alanine as a detector. Kirollos et al. is only concerned with the detection of gaseous pollutants, identified by a color change in the detection mechanism.

Morita et al. is cited in the Office Action for the teaching of a dosimeter including crystalline alanine. The dosimeter is used for measuring radiation exposure. A reading of the dosimeter exposure to radiation is made with an electron spin resonance instrument, as shown in the examples. Morita et al. does not disclose or suggest any marking on the dosimeter for any purpose.

Applicants claimed invention is directed to a dosimeter (claims 17-26) and a method of measuring an absorbed dose of radiation using such a dosimeter (claims 1-10, 12-16). The dosimeter comprises a support having a first region of alanine and a binder, and a second region having an identification mark. The first region absorbs ionizing radiation, which can be detected to determine the radiation level to which the support has been exposed. The second region includes an identifying mark and is distinct from the first region, though it may overlap the first region. The identifying mark does not change in response to radiation. As defined in the application at least at page 7, lines 10-13, the identifying mark contains information unique to the dosimeter to which it is attached, for example, a manufacturing lot number, a unique dosimeter identification number, or calibration information for the dosimeter.

The function of the identifying mark is to aid in identifying and tracking a specific dosimeter. The ability to identify a specific dosimeter discourages tampering. In practice, the dosimeter can be attached to goods, for example, a shipment of produce, and the identifying mark information recorded in association with that shipment number. The produce can then be irradiated and shipped to its destination, for example, the United States. At the receiving port, the second region of the dosimeter can be checked to verify that the identifying mark is the one associated with the goods at the point of origin, ensuring the dosimeter has not been switched in transit. The first region of the dosimeter can then be tested to ensure the radiation levels to which the goods have been exposed fall within an acceptable range under, for example, Food and Drug Administration

standards. Because of the manner in which alanine absorbs radiation, the total amount of radiation to which the dosimeter is exposed will be recorded, whether the radiation is received in one dose or multiple doses. The device and method as claimed herein ease tracking of irradiated goods by: 1) providing a reliable dosimeter for each unit of goods; and 2) providing an identifying mark that can be associated with the unit of goods, making tampering with the goods easier to detect. The dosimeter and method can also be used to measure radiation in a specific location, wherein the identifying mark can be used to prohibit tampering and/or indicate calibration information for the dosimeter, which is needed to determine an accurate reading of any dosimeter.

Kirollos et al. does not disclose or suggest measuring radiation. Further, the self-appearing warning sign of Kirollos et al. is directly linked to absorbed pollutant levels, changing color with increasing pollutant exposure. No identification mark separate from the pollutant detection means is disclosed or suggested on the device of Kirollos et al. Morita et al. does not disclose or suggest any identification mark on the alanine dosimeter described therein. If one skilled in the detection arts were to combine Kirollos et al. and Morita et al., one would not arrive at the claimed invention because neither reference discloses or suggests including a separate identification mark not tied to the detection means of the device. The combination of Kirollos et al. and Morita et al. instead suggests a color-change dosimeter, wherein the alanine, or a chromographic agent added thereto, would undergo a color change indicative of the level of radiation to which the dosimeter was exposed.

As described above, neither Kirollos et al. nor Morita et al., alone or in combination, disclose or suggest the claimed invention because neither reference discloses or suggests including an identification mark separate and distinct from the detection area of the device, and which serves a different purpose therefrom. For at least the above reasons, reconsideration and withdrawal of the rejection are in order, and are respectfully solicited.

Claims 17-26 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over Claims 1-8 and 10 of copending U.S. Application No. 09/995,088. In accordance with 37 CFR 1.321(c), enclosed is a Terminal Disclaimer which is believed to overcome the

provisional double patenting rejection. The Terminal Disclaimer is filed in order to further prosecution, and does not constitute an admission by Applicants as to double-patenting. Applicants retain the right to distinguish the subject matter of the above-identified application and U.S. Application No. 09/995,088. In view of the Terminal Disclaimer filed herewith, it is respectfully requested that the double patenting rejection be reconsidered and withdrawn.

For at least the reasons set forth above, Applicants submit all of Claims 1-10 and 12-26 are in condition for allowance. Prompt and favorable action are respectfully requested.

Should the Examiner require anything further, or have any questions, the Examiner is asked to contact Applicants' undersigned representative.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Kathleen Neuner Manne', is written over a horizontal line.

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